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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/733,166	12/08/2000	Richard W. Compans	96-99	2363

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EXAMINER
LI, BAO Q

ART UNIT	PAPER NUMBER
1648	23

DATE MAILED: 04/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/733,166	COMPANS ET AL.	
	Examiner	Art Unit	
	Bao Qun Li	1648	

-- The MAILING DATE of this communication appears on th cover sheet with th correspondence address --

Period for R ply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 February 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *62-69* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *62-69* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 62-69 are pending.

RCE

The request filed on 02/11/2003 for a request for continued examination (RCE) under 37 CFR 1.114 (d) is acceptable and a RCE has been established. An action on the RCE follows.

Response to Amendment

This is a response to the amendment, paper No. 22, filed 02/03/03. Claims 21-26, 29, 34-39 and 40 have been canceled. New claims 62-69 have been added. Claims 62-69 are considered before the examiner.

Because Applicants have canceled claims 21-26, 29, 34-39 and 40 in response to the previous Office Action, the issue related those claims would not be addressed.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

2. Claims 62-69 are still rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Claim 62 is confusing and unclear for the recitation of " composition comprising an antigen of an inactivated or attenuated virus and a hemagglutinin".

4. Applicants argue that the term of "inactivated or attenuated: as recited in the claim 62, are commonly used in the art and their meaning is readily understand by a skilled artisan. Furthermore, Applicants asserted that specification provides a specific example of an in vitro and in vivo assays used from confirmation of the inactivation of the influenza virus PR8/5 by formalin under certain condition. Therefore, claims 62-69 are considered to be defined and clear. The rejection should be withdrawn.

5. Applicants' argument has been fully considered; however, it is not found persuasive because the claimed invention does not read on a composition comprising an inactivated or attenuated virus, it read on an antigen of an inactivated or attenuated virus and the example provided by the specification does not support that the composition comprising an antigen of an inactivated or attenuated virus since the whole virus use in the example contains many antigens. Furthermore, it is unclear from the claimed language whether an antigen of an inactivated or attenuated virus and hemagglutinin in an isolated form or they are still within the construct of the whole virus. If they are still within the whole construct of the virus, how the claimed can be cited as an antigen of an inactivated or attenuated virus and a hemagglutinin because an inactivated or attenuated virus contained many antigens rather than a single antigen. Please clarify what structural relationship of claimed an antigen of an inactivated or attenuated virus with a hemagglutinin in the composition. Are they a mixture or two individual components or they are chemically or biologically associated each other because a hemagglutinin itself is an antigen. This affects the dependent claims 63-69.

Claim Rejections - 35 USC § 112

6. Claims 62-69are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for using a formalin inactivated influenza virus P8/5 to induce a serum immune response in a CD4 deficient mouse model, does not reasonably provide enablement for using an antigen and a hemogglutinin isolated from an inactivated of attenuated virus to induce a serum immune response in a CD4 deficient animal and human. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

7. Applicants submit that the previous rejected claims haven been canceled and new claims 62-69 are based on the inventor's discovery that the immune response can be induced in CD4+ T cell independent manner, contrary to the general belief in the filed at the time when the present invention was filed. Therefore, withdrawn the rejection is respectfully requested.

8. Applicants' argument has been respectfully considered; however, it is not found persuasive because the current enablement rejection is not based on that the specification does not teach a method of using a single antigen from an inactivated virus or attenuated virus plus a

hemagglutinin as an single component in the composition to induce a humoral immune response in a CD4+ T cell deficient animal or human. The detail action is as following:

9. Applicants are reminded that the test of scope of the enablement is whether one skilled in the art could make and use the claimed invention from the disclosures in the application coupled with information known in the art would undue experimentation (See United States v. Theketronic Inc., 8USPQ2d 1217 (fed Cir. 1988). Whether undue experimentation is required is not based upon a single factor but rather a conclusion reached by weighting many factors. Theses factors were outlined in Ex parte Forman, 230 USPQ 546 (Bd. Pat. App. & Inter. 1986) and gain in re Wands, 8USPQ2d 1400 (Fed. Cir. 1988). These factors are summarized according to the instant case as following

10. 1) & 2). State of the art and Unpredictable field.

11. The state of art teaches that antigens can be divided into a T cell dependent antigen and T cell-independent antigen. Antigens that stimulate antibody production in the absence of MHC class-II restricted T cell help are classified as T cell-independent (TI) antigens (Mond et al. (Annu. Rev. Immunol. 1995, Vol. 13, pp. 655-602, see lines 15-16 on page 655). TI antigen can be further subdivided into type I (TI-1) and type II (TI-2) antigens according to their ability to induce TI antibody response in mice with an X-linked immunodeficiency [CBA/N(xid/xid)] (XID mice). Only TI-1 but not TI-2 antigens induce antibody responses in the XID mice (Bachmann et al. Eur. J. Immunol. 1995, Vol. 25, pp. 3445-3451. See section of introduction on page 3445). Therefore, not every or all antigen is able to induce an humoral immune response in an T cell independent manner. Therefore, it is unpredictable to use any or all antigen for inducing an humoral immune response in a T cell independent manner as it is claimed in instant applicants. Therefore, without knowing the characteristic of each individual antigen, it is very unprecidatable whether an antigen is able to induce a immune response in a CD4+ deficient animal.

12. 3) & 4) Working example and amount of guidance:

13. The specification only presents that injection of a formalin-inactivated influenza virus PR/8 into CD4+ deficient mice induces a virus-specific humoral immune response. However, specification does not teach a method of using an antigen isolated from an inactivated or attenuated virus plus a hemagglutinin in an isolated form is able to induce a humoral response in

a CD4+ T cell deficient animal or human. Even claim 66 has further limited that the hemagglutinin is within the structure of the inactivated influenza virus, the specification does not provide an evidence which antigen plus the hemagglutinin are able to induce a humoral immune response in the CD4 deficient mouse model. Moreover, the scope of the claimed invention broadly read on the composition use for the claimed method comprising an antigen and a hemagglutinin, but the specification is deficient for showing the observed immunological effect is specifically produced by the combination of any isolated single antigen plus a hemagglutinin molecule as two components only present in composition. The claimed invention may be an applicants' assumption without any scientific evidence to verified that the observed phenomena is due to only an antigen and a hemagglutinin presence in the composition because Specification did not teach to use an isolated antigen from a formalin-inactivated influenza virus plus an individual hemagglutinin in an isolated form to test whether the combination is able to induce a humoral immune response in CD4+ deficient animal or human. Specification is also deficient for giving any guidance for which antigen in any given virus listed in claim 69 is intended.

14. 5) Scope of the claimed invention

15. Furthermore, the scope of claimed invention broadly read on a method for inducing a humoral immune response in a CD4+ T cell deficient condition in animal and human with a composition comprising any or all antigen of many inactivated or attenuated viruses as cited in claim 69 plus a hemagglutinin.

16. 6) & 7) Nature of the invention and level of skill in the art.

17. The invention involves one of complicated fields of producing an immune response in CD4 T cell deficient situation. Therefore, it requires a high level of the skill in the art to practice the broadly claimed invention.

18. Given the above analysis of the factors, which the courts have determined, are critical in asserting whether a claimed invention is enabled, it must be considered that the skilled artisan would have had to conduct undue and excessive experimentation in order to practice the claimed invention.

Claim Rejections - 35 USC § 112

19. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain **a written description** of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

20. Claims 62-69 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In the instant case, the subject matter of claimed method for using a composition comprising an antigen of an inactivated or attenuated virus and a hemagglutinin to induce a humoral immune response is not described.

21. In the instant case, the specification only describe a method of using a whole formalin inactivated influenza virus PR/8 to induce a humoral immune response in the $CD4^+$ T cell deficient mice. Applicants were not in the possession of a method for using a composition comprising a single antigen isolated from an inactivated or attenuated virus and a hemagglutinin to induce a humoral immune response in a CD4+ deficient animal or human. The whole virus of influenza contains many antigens, which include hemagglutinin molecule. The immunological effect present by the specification in the instant Applicants is brought by a formalin inactivated influenza virus, which contain a hemagglutinin and many viral antigens own by the whole influenza virus. This effect may depend on the presence of the totality of the whole influenza virus antigenicity, but not by one single antigen plus a hemagglutinin. The specification does not teach or describe how to use any single antigen of an inactivated or attenuated virus plus a hemagglutinin to induce a humoral immune response in CD4+ deficient animal and human being. The specification is also deficient for giving any guidance showing which antigen is a candidate having such an ability.

22. See *University of California v. Eli Lilly*, 119 F.3d 1559, 43 USPQ 2d 1398 (Fed, Cir. 1997):

> The name cDNA is not in itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant

> structural or physical characteristics; in other words, it thus does not describe human insulin cDNA .... Accordingly, the specification does not provide a written description of the invention ....

and at pg 1406:

> a generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA," without more, is not an adequate written description of the genus because it does not distinguish the genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicted, does not suffice to define the genus because it is only an indication of what the genes does, not what it is.

See also *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ 2d 1016 at page 1021:

> A gene is a chemical compound, albeit a complex one, and ... conception of a chemical compound requires that the inventor be able to define it so as to distinguish it from other materials .... Conception does not occur unless one has a mental picture of the structure of the chemical or is able to define it by its method of preparation, its physical or chemical properties, or whatever characteristics sufficiently distinguish it. It is not sufficient to define it solely by it principal biological property, *e.g.*, encoding human erythropoietin, because an alleged conception having no more specificity than that is simply a wish to know the identity of any material with that biological property.

The case law of *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997), and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ 2d 1016, which teach that the disclosure of a process for obtaining cDNA and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from that organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism. 35 USC 112 requires inter alia that "a patent specification contain a written description of the invention and the manner and process of making and using it in such full clear and concise terms as to enable one skilled in the art to make and use the invention". Case law has made it clear that the requirements for a "written description" and an "enabling disclosure" are separate. For example, where a specification contains sufficient information to enable a skilled chemist to produce a particular compound because it gives detailed information on how to produce analogous compounds but it makes no reference to the compound in question,

the "written description" requirement has not been met even though the description may be enabling. In the instant case, an antigen of an inactivated or attenuated virus used in the claimed method has not been described in the specification of the instant Application.

Claim Rejections - 35 USC § 102

23. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

24. In response to previous Office Action, Applicants have submit that the newly entered claims 62-69 are not anticipated by any of the cited references because the present invention claims a method for inducing immune response, not a composition, and thus the claims specially define limitations relevant fro making and using the invention. None of the cited art teaches or suggests such method that is drawn to a new method of inducing a humoral immune response in a subject deficient in CD4+ T cells by administering a certain antigen (e.g., an inactivated virus) that is not infectious to the subject. Nothing in the cited art mentions a link to such compromised condition of CD4 T cell deficient subject.

25. Applicants' argument has been respectfully considered, however, it is not found persuasive because the limitation of a subject deficient in CD4+ T cells in the preamble language is just an intended use of same structurally and functionally composition.

26. The following is language taken out of bristol-myers

27. Bristol-Myers Squibb Company v. Ben Venue Laboratories 58 USPQ2d 1508 (CAFC 2001).

28. Preamble language in claims of patents directed to administration of anticancer drug are expressions of purposes and intended results, and as such are non-limiting, **since language does not result in manipulative difference in steps of claims;** case does not present situation in which new use of process should be considered limiting because it distinguishes process over prior art and voluntary amendment adding preamble language, made after examiner indicated that claims were allowable, does not create material limitation.

29. In the instant case, the limitation of " wherein said human or animal has deficiency in CD4+ T cell" does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosure. In other ward, the claim language is only a statement of purpose and intended result. The expression does not result in a manipulative difference in the steps of the claims.

30. Furthermore, according to Applicant argument, if the claimed invention can be read that formalin inactivated influenza virus provide an antigen and a hemogglutinin for the composition used in the claimed method, therefore, the claimed invention would be still anticipated by the following prior art. The rejections based on the ***35 USC § 102*** follow:

31. Claims 62-66 and 68 are rejected under 35 U.S.C. 102(b) as being anticipated by Miotti et al. (JAMA 1989, Vol. 262, pp. 779-783).

32. Miotti et al. disclose a study of immunizing HIV infected patients with a vaccine composition comprising trivalent influenza subvirion vaccine containing 15 μg of the hemagglutinin of each of the following influenza virus strains: A/Taiwan/1/86(H1N1), A/Leningrad/360/86 (H3N2), and B/Am Arbor/1/86), in which the individual is HIV infected person with CD4+ T cell deficiency, the antigen and a hemagglutinin isolated from an inactivated influenza virus, which belong to an envelope virus of orthomyxovirus family (See section of vaccine from pages 779-780). The injection of the composition induces a humoral immune response in the patients (Table 1-4 on pages 780-782). Therefore, the claimed invention is anticipated by the cited reference.

33. Claims 62-65 and 68 are rejected under 35 U.S.C. 102(b) as being anticipated by Dominic et al. (Virol, Vol. 224, pp. 10-17).

34. Dominic et al. teach a method for inducing a humoral immune response in mice comprising injection an immunogenic composition consisting of a vaccine DNA encoding the influenza A/PR/8/34 (H1N1) HA gene, wherein the HA gene encoding the antigenic protein of hemagglutinin of influenza virus. After injection the composition, HA-specific IgG has been detected in the animal sera (See section of Materials and methods on pages 10-11 and section of maintenance of sera antibodies to HA in mice vaccinated with HV DNA on page 12) . Therefore, the claimed invention is anticipated by the cited reference.

35. Claims 62-69 are rejected under 35 U.S.C. 102(b) as being anticipated by Compans et al. (US patent No. 4,790,987A).

36. Compans et al. disclose a method for using a composition for immunizing the animal or human to protect a influenza virus infection. One of the compositions used in the vaccination procedure is disclosed as a formalin-inactivated influenza virus (lines 52 on col. 11 through lines 40 on col. 12), which inherently comp irises an antigen of the formalin-inactivated influenza virus and a hemagglutinin that is comprised within the inactivated influenza virus. The other embodiment of the clamed invention disclosed by Compans et al. also include a composition and a method for using a composition to prevent a virus, including herpesvirus, HIV rabies virus, wherein the composition comprising at least one immunnogenic (F) fusion viral envelope glycoprotein and at least one immunogenic (HN) receptor-biding viral envelope glycoprotein, wherein the HN is referred to hemagglutinin/neuraminidase of parainfluenza. Therefore, the claimed invention is anticipated by the cited prior art.

37. Claims 62-64 and 67-68 are rejected under 35 U.S.C. 102(b) as being anticipated by Murphy et al. (Vaccine 1990, Vol. 8, pp. 497-502).

38. Murphy et al. teach a method for immunization animal rats with a formalin-inactivated respiratory syncytial virus (RSV) or purified F glycoprotein, in which the formalin-inactivated RSV comprising an antigen of inactivated RSV and hemagglutinin because the hemagglutinin is the component of RSV (See section of materials and methods on page 498). After immunization, a neutralizing antibody, which represent the humoral immune response were observed and measured in the animals (See Table 1. on page 499). Therefore, the claimed invention is anticipated by the cited reference.

39. Claims 62-65 and 68-69 are rejected under 35 U.S.C. 102(b) as being anticipated by Muster et al. (J. Virol. 1994, Vol. 68, pp. 4031-4034).

40. Muster et al. teach a chimeric influenza virus, which comprises an ectodomain of HIV-1 gp41 antigen 2F5 epitope sequence of ELDKWA inserted into the loop of antigenic site B of the influenza virus hemagglutinin. The antigen composition therefore, comprises an antigen of an inactivated HIV, which is an envelope protein and hemagglutinin, which is still within the body of the chimeric influenza virus vector. The resulting chimeric influenza virus was able to elicit

ELDKWA-specific immunoglobulins G and A in the antisera of mice. (See entire document). Therefore, the claims are anticipated by the cited prior art.

41. Claims 62-66 and 68-69 are rejected under 35 U.S.C. 102(b) as being anticipated by Li et al. (J. Virol. 1993, Vol. 67, pp. 6659-6666).

42. Li et al. teach a method for inducing an humoral immune response by using a composition comprising a chimeric influenza vector that expresses a 12-amino acids peptide derived from V3 loop of gp120 of HIV-1. This peptide is inserted into the loop of antigen site B of influenza A/WSN/33 virus hemagglutinin (HA). The antigen composition therefore, comprises an antigen of an inactivated HIV, which is an envelope protein and hemagglutinin, which is still within the body of the chimeric influenza virus vector. Mice immunized with the chimeric virus produce anti-HIV antibody and CTL, which recognizes the HIV virus. Therefore, the claimed invention is anticipated in the cited reference.

43. Claims 62-66 and 68-69 are rejected under 35 U.S.C. 102(b) as being anticipated by Pales et al. (J. Inf. Dis. 1997, Vol. 176 (Suppl 1), pp. S45-S49).

44. Pales et al. teach several methods for inducing a immune response of a long-lasting HIV-specific serum antibodies by using an live attenuated influenza virus as a vector carrying an HIV antigen ELDKWA. The attenuated influenza virus containing hemagglutinin (HA) and neuraminidase genes (NA). The composition used for inducing the humoral immune response comprises an antigen and a hemagglutinin, which is still within the construct of the attenuated influenza virus (See entire document). Therefore, the claimed invention is anticipated by the cited reference.

45. Claims 62-68 are rejected under 35 U.S.C. 102(b) as being anticipated by Budowsky et al. (Vaccine 1993, Vol. 11, pp. 343-348).

46. Budowsky et al. teach a method for immunization animal mice with a beta-propiolactone (PL) -inactivated influenza virus, in which the inactivated influenza virus comprising an antigen and hemagglutinin (See section of materials and methods on page 344). After immunization, a neutralizing antibody against hemagglutinin has been detected in the sera of the mice (Fig. 1 and 2 on page 345), which represent the humoral immune response. Therefore, the claimed invention is anticipated by the cited reference.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 703-305-1695. The examiner can normally be reached on 7:00 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Bao Qun Li
April 1, 2003

JAMES HOUSEL 4/7/03
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600